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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,245	05/09/2001	N. Leigh Anderson	2316-147	4784

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	

ART UNIT	PAPER NUMBER
1753	B

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/851,245	ANDERSON ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7 and 28-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,29 and 31-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

1. Applicant's amendment of September 08, 2003 does not render the application allowable.

Response to Arguments

2. Applicant's arguments filed September 08, 2003 have been fully considered but they are not persuasive. Applicant requests that the following rejections under 35 U.S.C. 103(a) be withdrawn

the rejection of claims 1-5, 10-16, 20, 22-24, and 26 over Ando in view of Minden; and

the rejection of claims 6-9, 18, and 19 over Ando in view of Minden, Lugojan, and Allen.

Applicant asserts that the above rejections should be withdrawn because "[t]he Ando reference discloses scanning of an array to extract an electrophoresis pattern, but fails to disclose removal of spots represented by the extracted pattern," and the supporting references fail to remedy this deficiency. The examiner respectfully disagrees.

The examiner has had a Japanese translator at the Patent and Trademark Office review and verbally interpret the Ando Japanese patent and the examiner has had a written translation of the Ando Japanese patent prepared (a copy of which is included with this Office action), which is independent of the translation by the translator at the Patent and Trademark Office. Both the interpretation by the Japanese translator at the Patent and Trademark Office and the written translation agree that Ando teaches extracting images of the separated biomolecules ***and*** actual physical extraction of the separated biomolecules. Applicant is referred to Claims 1-3 and

paragraphs [0001] and [0006] of the Detailed explanation of the invention in the written translation, which teach extracting, that is, physically removing, separated biomolecules from the gel. Paragraph [0014] of the Detailed explanation of the invention teaches including a sampler function allowing the sampler head to move up-and-down so that desired molecules may be extracted. Figure 3 shows extracted molecules being deposited in a container which has compartments for holding various extracted biomolecules. Thus, the Ando reference clearly teaches removal of spots represented by the image of the extracted pattern.

It will be noted that the written translation of the Ando reference is consistent with the machine translation cited in the challenged rejections. Clams 1-3, for example, of the machine translation tracks Claims 1-3 of the written translation fairly well. Physically removing desired biomolecules after imaging them is clearly taught in the machine translation of Ando. For example, see paragraphs [0013]-[0015] of the *Detailed Description*. The written translation thus validitates the teaching of the machine translation of the Ando patent cited in the rejections.

Status of Rejections pending since the Office action of April 08, 2003

3. The rejection of claims 6, 8, and 9 under 35 U.S.C. 112, first paragraph, is withdrawn.

4. The rejection of claim 25 under 35 U.S.C. 112, first paragraph, is withdrawn.

5. The rejection of claim 27 under 35 U.S.C. 112, first paragraph, is withdrawn.

6. The double patenting rejections of claims 1-5, 10-17, 23, and 26 over U.S. Patent No. 6,451,189 are withdrawn.

7. The double patenting rejections of claims 1-5, 10-17, 23, and 26 over U.S. Patent No. 6,507,664 are withdrawn.

8. The double patenting rejections of claims 1-5, 10-17, 22, 23, and 26 over U.S. Patent No. 6,398,932 are withdrawn.

9. The rejection of claims 1-5 under 35 U.S.C. 103(a) as being obvious over the JPO machine translation of Ando in view of Minden et al. is maintained.

10. The rejection of claims 6 and 7 under 35 U.S.C. 103(a) as being obvious over the JPO machine translation of Ando in view of Minden et al. and further in view of Lugojan and Allen et al. is maintained.

11. The rejections against any claims cancelled by Applicant are withdrawn.

12. The rejections that are maintained have been restated below for Applicant's convenience and modified to address Applicant's new claims.

Double Patenting

13. Claim 29 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 3. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

14. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 34 effectively requires, prior to isolation with the robotic device, separating the polyacrylamide gel from the solid support by breaking covalent bonds between the polyacylamide gel and the solid support. No support has been found for this step in the original disclosure. Original claim 22 actually requires placing the gel *onto* a solid support prior to moving the cutter into the gel.

15. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. Claim 34 effectively requires, prior to isolation with the robotic device, separating the polyacrylamide gel from the solid support by breaking *covalent* bonds between the polyacylamide gel and the solid support. While mechanical and chemical means are known in the art for removing a gel from a solid support to which it has been covalently bonded, these are generally destructive means, which will largely destroy the gel, and are performed after detection or isolation of the of the biomolecules of interest. One with ordinary skill in the art would not know how to remove prior to isolation a polyacrylamide gel from a solid support prior to which it has been covalently bonded without damaging the gel.

Claim Rejections - 35 USC § 103

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

17. Claims 1-5, 29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO machine translation of Ando (JP 07260742 A) in view of Minden et al. (US 6,043,025).

Addressing Claims 1 and 29, Ando teaches a computer-assisted method for selecting and directing the isolation of one or more biomolecules, such as protein or DNA, in an array (the abstract and paragraph [0001] of *Detailed Description*), comprising

imaging the array to generate a computer-readable output comprising, for each of a plurality of biomolecules detected in the array, a pair of x,y coordinates and a signal value;

processing the output in at least one computer to select one or more of the detected biomolecules in accordance with previously ordained or operator-specified criteria, and

generating machine-readable instructions that direct a robotic device to isolate at least one of the selected biomolecules form the two-dimensional array.

See paragraphs [0008]-[0018] of the "Detailed Description."

Ando do not mention performing two-dimensional electrophoresis, specifically the purification and first and second separation steps of Applicant's claim 1 and 29, although Ando does disclose electrophoresing protein ("Technical Field").

Minden et al. teach substantially isolating biomolecules of interest from a biological sample and performing a first and a second separation step on these biomolecules. See the abstract; Figure 1; and col. 9, ll. 33-46. It would have been obvious to one with ordinary skill in the art at the time the invention was made to purify the biomolecules of interest before performing electrophoresis as taught by Minden et al. in the invention of Ando because this will avoid introducing interferants and contaminants into the electrophoresis system. It would have been obvious to one with ordinary skill in the art at the time the invention was made to perform a

first separation step and a second separation step as taught by Minden et al. in the invention of Ando because as taught by Minden et al. "[t]wo dimensional gel electrophoresis has been a powerful tool for resolving complex mixtures of proteins" (col. 2, ll. 40-41).

Addressing Claim 2, isolating a selected biomolecule as claimed is implied by paragraphs [0012]-[0014] of Ando, which teaches extracting a selected biomolecule after imaging the gel.

Addressing Claims 3, Ando disclose analyzing proteins in the section entitled "Technical Field." Additionally, Minden et al. teach separating proteins. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have the biomolecules (macromolecules) be proteins as taught by Minden et al. in the invention of Ando because as taught by Minden et al. analysis of proteins can be a valuable source of information and a valuable diagnostic tool (col. 1, ll. 15-25).

Addressing claim 4, Ando as modified by Minden et al. use polyacrylamide to perform the two-dimensional electrophoresis (col. 10, ll. 15-22 in Minden et al.).

Addressing Claim 5, Ando as modified by Minden et al. perform two-dimensional SDS polyacrylamide electrophoresis (col. 10, ll. 15-22 and col. 1, ll. 26-38 in Minden et al.).

Addressing Claim 31, as taught by Minden et al. (and commonly practiced in the art) 2D gel electrophoresis involves separation by isoelectric focusing followed by separation by size, such as with SDS (col. 1, ll. 26-38 and col. 1, ll. 59-66).

18. Claims 6, 7, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over JPO machine translation of Ando (JP 07260742 A) in view of Minden et al. (US 6,043,025) as applied to claims 1-5, 25, 29, and 31 above, and further in view of Lugojan (US 5,543,023) and Allen et al. (US 4,746,551).

Addressing claims 6, 7, and 32, Ando as modified by Minden et al. do not appear to mention the composition of the gel support used. Glass and plastic are the most commonly used materials from which gel supports are made. If a glass support is used then the polyacryalmide will covalently bond to the support (col. 3, ll. 1-3 in Allen et al.). If the support is made of another material, such as plastic, it would have been obvious to one with ordinary skill in the art at the time the invention was made to bond the gel to the support, using, for example, Gelbond®, as taught by Lugojan (col. 4, ll. 29-37) because then the gel will not slide about, which could distort the imaging of the gel or the isolation of selected biomolecules.

Addressing Claim 33, isolating a selected biomolecule as claimed is implied by paragraphs [0012]-[0014] of the *Detailed Description* Ando, which teaches extracting a selected biomolecule after imaging the gel.

19. Claims 30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO machine translation of Ando (JP 07260742 A) in view of Minden et al. (US 6,043,025) as applied to claims 1-5, 29, and 31 above, and further in view of Liu et al. (US 5,492,834). Ando as modified by Minden et al. does not mention purifying the biological sample with a size exclusion column; that is, by size exclusion column chromatography. Liu et al. teaches purifying a biological sample with a size exclusion column before performing electrophoresis analysis (abstract and claim 12). It would have been obvious to one with ordinary skill in the art at the time the invention was made to purify the biological sample with a size exclusion column as taught by Liu et al. in the invention of Ando as modified by Minden et al. because as taught by Liu et al. interferants in a biological sample, particularly low molecular weight compounds in high concentrations, can substantially interfere with separation and detection of the proteins of interest (col. 2, ll. 19-41).

20. The following is a statement of reasons for the indication of allowable subject matter: in Ando as modified by Minden et al., Lugojan, and Allen et al. the gel is not separated from the solid support prior to isolation with the robotic device.

Final Rejection

21. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola

Alex Noguerola
11/18/03
Primary Examiner
TC1753